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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,599	06/28/2000	Wayne H. Kaesemeyer	25795-2	5779

7590

03/29/2002

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/29/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/605,599

Applicant(s)

KAESEMEYER, WAYNE H.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-20 are pending.
2. Claims 1-20 are rejected.

Response to Arguments

3. Applicant's arguments filed January 3, 2002 have been fully considered but they are not persuasive with respect to composition claims 13-20. Applicants argue that Usala analogs are inhibitors of scavengers and also that the instant claims have been amended to recite "therapeutically effective amounts of L-arginine".

4. In response to applicant's first argument that Usala analogs are inhibitors of scavengers, it is noted that claims 13-20 are composition claims and accordingly an intended use of composition claims does not provide patentable distinction over the prior art. Applicant attempted to limit the composition claims with the incorporation of the phrase "therapeutically effective amounts of L-arginine". However, it is noted that Usala also teaches of a therapeutic composition, which contains the amino acid of L-arginine, and that it contains an effective amount of the L-arginine, (see column 16, 12-13).

Specification

5. The substitute specification of January 3, 2002 has been received and entered.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. The rejection of claims 1-20 under 35 U.S.C. 102(e) as being clearly anticipated by Usala of U.S. Patent No. 5,824,331 is withdrawn in view of the amendment filed on January 3, 2002. However, due to the amendment of January 3, 2002, the composition claims, specifically claims 13-20, are still rejected by the prior art reference of Usala by now under 35 U.S.C. 103(a), (see paragraph No. 10 in this Office Action).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usala of U.S. Patent No. 5,824,331. Usala teaches of a composition, which contains L-

arginine in a sustained –polymeric release matrix, (see abstract, columns 2-4 and claims 1-51). Usala is directed also directed to a method of therapeutic use and for this reason Usala does provide a therapeutic amount of the amino acid, such as amounts ranging from 0 to 300 mM, (see column 16, 12-13).

11. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollace et al. in view of Conte et al. Mollace et al. teach of the administration of L-arginine, (see abstract). Conte et al. teach that it is well known to put a pharmaceutical in an extended-release dosage, (see entire article). The determination of a dosage having the optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Hence, the references make obvious the instant invention.

12. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. in view of Conte et al. Cook et al. teach of the administration of L-arginine improves endothelium-dependent vasorelaxation which is associated with a reduction in atherogenesis, (see abstract). Conte et al. teach that it is well known to put a pharmaceutical in an extended-release dosage, (see entire article). The determination of a dosage having the optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Hence, the references make obvious the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-

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4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614

March 25, 2002